

# EXHIBIT 2



U.S. Food & Drug Administration

## Inspections, Compliance, Enforcement, and Criminal Investigations

Home Inspections, Compliance, Enforcement, and Criminal Investigations Enforcement Actions Warning Letters

Dr Pepper Snapple Group 8/30/10



Department of Health and Human Services

Public Health Service  
 Food and Drug Administration  
 College Park, MD 20740

AUG 30 2010

### WARNING LETTER

#### CERTIFIED MAIL RETURN RECEIPT REQUESTED

Mr. Larry D. Young  
 President and CEO  
 Dr Pepper Snapple Group  
 5301 Legacy Drive  
 Plano, Texas 75024

Re: CFSAN-OC-10-26

Dear Mr. Young:

The Food and Drug Administration (FDA) has reviewed the label for your Canada Dry Sparkling Green Tea Ginger Ale. We examined the product label and your website at [www.canadadry.com](http://www.canadadry.com) in July of 2010. Based on our review, we have concluded that your green tea ginger ale product is in violation of the Federal Food, Drug, and Cosmetic Act (the Act). You can find the Act and regulations on FDA's website at [www.fda.gov](http://www.fda.gov).

Your Sparkling Green Tea Ginger Ale is misbranded within the meaning of section 403(r)(1)(A) of the Act [21 U.S.C. § 343(r)(1)(A)] because the product label bears a nutrient content claim that is not authorized by regulation. Under section 403(r)(2)(A)(i) of the Act, a claim that characterizes the level of a nutrient which is of the type required to be in the labeling of the food must be made in accordance with a regulation promulgated by the Secretary (and, by delegation, FDA) authorizing the use of such a claim. The use of a term, not defined by regulation, in food labeling to characterize the level of a nutrient misbrands a product under section 403(r)(1)(A) of the Act.

Your Sparkling Green Tea Ginger Ale bears the claim, "ENHANCED WITH 200 mg OF ANTIOXIDANTS FROM GREEN TEA & VITAMIN C\*\*" with the double asterisk referring to the statement, "\*\* Each 8 oz serving contains 200 mg of antioxidants from Green Tea Flavonoids and Vitamin C" on the principal display panel of the product label. In the context of this label the term "enhanced" is an unauthorized synonym for a "more" nutrient content claim. FDA has defined the nutrient content claim "more" and its authorized synonyms in 21 CFR 101.54(e). "More" nutrient content claims may be used on the label or in the labeling of foods to describe the level of nutrients, provided that (1) the food contains at least 10 percent more of the Reference Daily Intake or Daily Reference Value for the nutrient per reference amount customarily consumed than an appropriate reference food, (2) where the claim is based on nutrients that are added to the food, that the fortification is in accordance with the policy on fortification of foods in 21 CFR 104.20, and (3) the claim bears the required information for relative claims as described in 21 CFR 101.130(2) and 101.54(e)(1)(iii).

Your Sparkling Green Tea Ginger Ale is a carbonated beverage. The policy on fortification in 21 CFR 104.20(a) states that the FDA does not consider it appropriate to fortify snack foods such as carbonated beverages. Additionally, the label of your product does not state the identity of a reference food and the percentage (or fraction) of the amount of the nutrient(s) in the reference food by which the nutrient(s) in the labeled food differs, as is required for "more" nutrient content claims under 101.130(2). Therefore, even if the term "enhanced" was an authorized synonym for "more," your product would not meet the requirements for a "more" claim under 21 CFR 101.54(e)(1).

Nutrient content claims using the term "antioxidant" must also comply with the requirements listed in 21 CFR 101.54(g). These requirements state, in part, that for a product to bear such a claim, a Reference Daily Intake (RDI) must have been established for each of the nutrients that are the subject of the claim (21 CFR 101.54(g)(1)), and these nutrients must have recognized antioxidant activity (21 CFR 101.54(g)(2)). The level of each nutrient that is the subject of the claim must also be sufficient to qualify for the claim under 21 CFR 101.54(b), (c), or (e) (21 CFR 101.54(g)(3)). For example, to bear the claim "high in antioxidant Vitamin C," the product must contain 20 percent or more of the RDI for Vitamin C under 21 CFR 101.54(b). Such a claim must also include the names of the nutrients that are the subject of the claim as part of the claim or, alternatively, the term "antioxidant" or "antioxidants" may be linked by a symbol (e.g., an asterisk) that refers to the same symbol that appears elsewhere on the same panel of the product label, followed by the name or names of the nutrients with recognized antioxidant activity (21 CFR 101.54(g)(4)). The use of a nutrient content claim that uses the term "antioxidant" but does not comply with the requirements of 21 CFR 101.54(g) misbrands a product under section 403(r)(2)(A)(i) of the Act [21 U.S.C. § 343(r)(2)(A)(i)].

The nutrient content claim for your Sparkling Green Tea Ginger Ale product of "ENHANCED WITH 200 mg OF ANTIOXIDANTS FROM GREEN TEA & VITAMIN C\*\* .... \*\*Each 8 oz serving contains 200 mg of antioxidants from Green Tea Flavonoids and Vitamin C" identifies Vitamin C as a nutrient associated with the antioxidant claim. Vitamin C is a nutrient that is a recognized source of antioxidants. Your Nutrition Facts panel declares Vitamin C at 100% of the Daily Reference Value (DRV), which accounts for 60 mg of the claimed 200 mg of antioxidants. According to the nutrient content claim on your product label, the remainder 140 mg of antioxidants must be derived from green tea or green tea flavonoids, which are not nutrients with recognized antioxidant activity under 21 CFR § 101.54(g)(2). Therefore, the claim "ENHANCED WITH 200 mg OF ANTIOXIDANTS FROM GREEN TEA & VITAMIN C\*\* .... \*\*Each 8 oz serving contains 200 mg of antioxidants from Green Tea Flavonoids and Vitamin C" does not

meet the requirements of 21 CFR 101.54(g) and misbrands your product under section 403(r)(1)(A) of the Act [21 U.S.C. § 343(r)(1)(A)].

The above violations are not meant to be an all-inclusive list of deficiencies in your products or their labeling. It is your responsibility to ensure that all of your products are in compliance with the laws and regulations enforced by FDA. You should take prompt action to correct these violations. Failure to promptly correct these violations may result in regulatory actions without further notice, such as seizure and/or injunction.

Please respond to this letter within 15 days from receipt with the actions you plan to take in response to this letter, including an explanation of each step being taken to correct the current violations and prevent similar violations. Include any documentation necessary to show that correction has been achieved. If you cannot complete corrective action within fifteen working days, state the reason for the delay and the time within which you will complete the correction.

You should direct your written reply to Judith G. Dausch, Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, Office of Compliance (HFS-608), Division of Enforcement, College Park, Maryland 20740-3835.

Sincerely,

/s/

Jennifer Thomas  
Acting Director  
Office of Compliance  
Center for Food Safety  
and Applied Nutrition

cc: FDA Dallas District

Links on this page:

1. <http://www.canadadry.com>
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